K070587
510(k) Summary

APR 10 2008

I. General Information on Submitter

Product Name: Elegance Woman's Lubricant
Contact Person: Julie Williams, PA-C
Address: 1209 Robin Trail
Round Rock, TX 78681 USA
Telephone: 512.294.1133
Fax: 512.388.5869
Email: president@eleganceinfo.com

Date Prepared: February 10, 2007

II. General Information on Device

Trade Name: Elegance Woman's Lubricant
Common Name: Vaginal lubricant
Classification Name: Lubricant, Vaginal, Patient
(21 CFR 880.6375, Product Code: MMS)

III. Predicate Devices

Predicate Device 510 (k) control #
K-Y™ Liquid Personal lubricant (K955648) LifeStyles®
Liquid Personal Lubricant (K033076) Durex Play™
Personal Lubricant (K032124)

IV. Description of Device

Elegance Woman's Lubricant is a non-sterile oil-based personal lubricant formulated to supplement the body's own natural lubricating fluids to provide personal lubrication when vaginal dryness causes discomfort.

Ingredients

Natural oils of plant origin: *Glycine* Willd (soy), *Carthamus tinctorius* L.(safflower), and *Vitis vinifera* (grapeseed).

V. Intended Use

This product is a non-sterile, oil-based personal lubricant formulated to supplement the body's own natural lubricating fluids. Elegance Woman's Lubricant is a non-sterile, oil-based personal lubricant formulated to supplement the body's own natural lubricating fluids to provide personal lubrication when vaginal dryness causes discomfort.

The formulation does not harm vaginal or penile tissue.

VI. Technological Characteristics of Device Compared to Predicate Devices

Elegance Woman's Lubricant shares the following technological characteristics with the predicate devices: highly lubricious, medium-high to high viscosity, liquid, clear, non-irritating, and non-sterile. Although different ingredients were used, all ingredients are found to be Generally Recognized as Safe (GRAS).

This product has not been shown to be compatible with condoms. Labeling will contain a warning to this effect.

VI. Summary of Clinical Performance

Non-clinical evidence demonstrates biocompatibility and found no skin irritation or sensitivity. Subject-use reports demonstrate that Elegance Woman's Lubricant is nonirritating and effective as a personal lubricant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2014

Julie Williams, PA-C
Owner/Designer
1209 Robin Trail
ROUND ROCK TX 78681

Re: K070587
Trade/Device Name: Elegance Woman's Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated (Date on orig SE ltr): March 28, 2008
Received (Date on orig SE ltr): March 31, 2008

Dear Ms. Williams:

This letter corrects our substantially equivalent letter of April 10, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070587

Device Name: Elegance Woman's Lubricant

Indications for Use: Elegance Woman's Lubricant is a non-sterile, oil-based personal lubricant formulated to supplement the body's own natural lubricating fluids to provide personal lubrication when vaginal dryness causes discomfort.

Warning: Do not use this lubricant with condoms. It may weaken the condom's physical properties and make it more likely to break.

Prescription Use _____ AND/OR Over-The-Counter Use ___✓___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070587